

**2003 0232765**

1. A composition comprising a N-(4-chloro-3-(trifluoromethyl)phenyl)-N'-(4-(2-(N-methylcarbamoyl)-4-pyridoxy)phenyl)urea or a pharmaceutically acceptable salt thereof and a cytotoxic or cytostatic agent selected from the group consisting of: irinotecan, vinorelbine, gemcitabine, gefitinib, paclitaxel, and doxorubicin.
2. The composition according to claim 1, in combination with one or more pharmaceutically acceptable carrier molecules.
3. The composition of claim 1, wherein said pharmaceutically acceptable salt of N-(4-chloro-3-(trifluoromethyl)phenyl)-N'-(4-(2-(N-methylcarbamoyl)-4-pyridoxy)phenyl)urea is a tosylate salt.
4. A composition according to claim 1, in the form of an oral, intramuscular, intravenous, subcutaneous, or parenteral dosage which can range from about 0.1 to about 300 mg/kg of total body weight of N-(4-chloro-3-(trifluoromethyl)phenyl)-N'-(4-(2-(N-methylcarbamoyl)-4-pyridoxy)phenyl)urea and from about 0.1 to about 300 mg/kg of total body weight of a cytotoxic or a cytostatic agent.
5. A method for treating a cancer comprising administering a therapeutically effective amount of a composition comprising N-(4-chloro-3-(trifluoromethyl)phenyl)-N'-(4-(2-(N-methylcarbamoyl)-4-pyridoxy)phenyl)urea or a pharmaceutically acceptable salt thereof and a cytotoxic or cytostatic agent selected from the group consisting of: irinotecan, vinorelbine, gemcitabine, gefitinib, paclitaxel, and doxorubicin.
6. The method of claim 5, wherein said pharmaceutically acceptable salt of N-(4-chloro-3-(trifluoromethyl)phenyl)-N'-(4-(2-(N-methylcarbamoyl)-4-pyridoxy)phenyl)urea is a tosylate salt.
7. The method of claim 5, wherein said cancer is mediated by raf kinase.

8. The method of claim 5, wherein said cancer is colon, gastric, lung, pancreatic, ovarian, prostate, leukemia, melanoma, hepatocellular, renal, glioma, mammary, or head and neck cancer.

9. The method of claim 5, wherein said composition is administered to a patient at an oral, intramuscular, intravenous, subcutaneous, or parenteral dosage which can range from about 0.1 to about 300 mg/kg of total body weight of N-(4-chloro-3-(trifluoromethyl)phenyl-N'-(4-(2-(N-methylcarbamoyl)-4-pyridoxy)phenyl)urea and from about 0.1 to about 300 mg/kg of total body weight of a cytotoxic or a cytostatic agent.

10. A composition comprising a tosylate salt of N-(4-chloro-3-(trifluoromethyl)phenyl-N'-(4-(2-(N-methylcarbamoyl)-4-pyridoxy)phenyl)urea and a cytotoxic or cytostatic agent selected from the group consisting of: irinotecan, vinorelbine, gemcitabine, gefitinib, paclitaxel, and doxorubicin.

11. A method for treating a cancer comprising administering a therapeutically effective amount of a composition comprising a tosylate salt of N-(4-chloro-3-(trifluoromethyl)phenyl-N'-(4-(2-(N-methylcarbamoyl)-4-pyridoxy)phenyl) and a cytotoxic or cytostatic agent selected from the group consisting of: irinotecan, vinorelbine, gemcitabine, gefitinib, paclitaxel, and doxorubicin.

12. A method for inhibiting the proliferation of cancer cells in a patient comprising contacting said cancer cells with a pharmaceutical preparation comprising the composition of claim 1.